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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,447	08/20/2003	Ricky W. Purcell	1443.051US1	7982

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,447	PURCELL, RICKY W.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 February 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 32-62 is/are pending in the application.
- 4a) Of the above claim(s) 32-39 and 49-62 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 40-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/15/2004.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's election filed 02/07/2007, preliminary amendment filed 05/02/2006, and IDS filed 11/15/2004.

Claims 32-62 are pending.

Response to Election/Restrictions

1. Applicant's election with traverse of Group II, claims 40-48 in the reply filed on 02/07/2007 is acknowledged. The traversal is on the ground(s) that the entire application can be examined without burden on the examiner as the groups do not have distinct design as all recite first and second patch, and searching groups II and IV (that further require flexible wrap) will require searching groups I and III. This is not found persuasive because the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however they are extensive since the patent examiner searches the databases mostly literally. The prior art that anticipate groups I and III that require first and second patch may not anticipate groups II and IV that require fist patch, second patch and flexible wrap. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows

Art Unit: 1615

the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present four distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 32-39, 49-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/07/2007.

Claims 40-48 are included in the prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re*

Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides system for providing therapy to a portion of the body, the system comprises holder, first exothermic patch, second endothermic patch, and flexible wrap, and possible third analgesic patch.

(2) The state of the prior art

The system of the invention is multi-patch system. The art recognized multi-patch system as disclosed by US 4,592,358 and US 2002/0052569. The art further recognized analgesic patches provided with exothermic or endothermic means such US 6,245,347.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

Art Unit: 1615.

(4) The predictability or unpredictability of the art

The unpredictability of transdermal delivery is very high. The synergism and effect of heat and cold on the delivery of different drugs varies, and controlled by many factors including the solubility of the drug, the formulation containing the drug, the inclusion of permeation enhancers, the vascularity of the skin underneath the patch, etc. The effects of exothermic and endothermic patches depends on their structure that can be electric heaters, exothermic chemically activated patches, hot/cold water packs, ice pack, thermo-gels, etc. According to the intended use and area to be treated, the transdermal patches including exothermic and endothermic patches will vary widely.

(5) The breadth of the claims

The claims are very broad. The claims encompass all kind of patches and packs that used to treat any part of the body, including drug delivery patches, exothermic patches or packs, endothermic patches or packs. The specification disclosed patch to mean packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy, page 5, lines 11-12. Therefore, the breadth of the claims is exacerbated by disclosure.

(6) The amount of direction or guidance presented

The specification disclosed patch to mean packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy, page 5, lines 11-12. The specification provides no guidance, in the way

written description, patches including exothermic, endothermic, or analgesic patches in terms of structure, type, constituents, etc., that are suitable to practice the present invention. The patches according to applicant's disclosure can be any devices applied to the injured part that may encompass myriad of devices including transdermal therapeutic patches or devices, ice bag, or household heating bag. The specification did not describe how to make any of the claimed patches or how to use them in order to obtain therapeutic effect. The specification did not disclose how to use the patches to provide cumulative or synergistic effect. For example, the specification does not provide any written description for any of the patches used to practice the present invention or how to use the patches in correlation. Sometimes excessive heating may not be beneficial for delivering some analgesics, and may cause overdosage of analgesics if not controlled. On the other hand, cooling may cause vasoconstriction of cutaneous and subcutaneous blood vessels, and may reduce analgesic absorption through the skin. Additionally, exothermic patches may need activation by atmospheric oxygen, and wrapping such patches may hinder their function. The specification did not describe how to use the three patches in order to achieve therapeutic effect. Therefore, it is not obvious from the disclosure of one holder holding three patches, what kind of exothermic, endothermic or analgesic patches will work, and how they will work. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the elements fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

(7) The presence or absence of working examples

As stated above, the specification does not provide working examples to show how to make the claimed three types of patches or how to use them.

(8) The quantity of experimentation necessary

Since the structure of exothermic, endothermic and analgesic patches cannot be predicted a priori but must be determined from the case to case, and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue experimentation to determine which structure of each patch can be used to achieve a specific therapeutic effect and how to use the three kind of patches together in the holder to achieve the desired effect.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "near portion of the body" does not set forth the metes and bounds of the claims. Recourse to the specification, does not define the expression.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 32-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/954,764 in view of US 5,741,510 (510). The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: system and kit comprising holder, first exothermic patch (recited by claims 3 and 17 of the copending application), second endothermic patch (recited by claims 4 and 18 of the copending application), and third analgesic formulation.

The difference between the present claims the conflicting claims of the copending application is that the analgesic formulation instantly claimed is analgesic patch and the copending application recite the analgesic formulation as oral formulation.

US '510 teaches topical analgesic patch that has the advantage of providing excellent sustained release properties during the period of use and is more also comfortable and well tolerated by patients (abstract; col.1, lines 33-36, 47-50; col.2, lines 24-26).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide system for providing therapy to part of the body comprising holder, exothermic patch, endothermic patch, and analgesic formulation as claimed by the copending claims, and replace or select the topical analgesic patch formulation disclosed by US '510 as an analgesic formulation, motivated by the teaching of US '510 that topical analgesic patches are advantageous because they provide excellent sustained release properties during the period of use and are more comfortable and well tolerated by patients, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic patch, endothermic patch, and analgesic patch that successfully provides excellent sustained release properties during the period of use and are more comfortable and well tolerated by patients.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 40, 41, 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,592,358 ('358).

Present claim 40 is directed to system comprising first patch, second patch and flexible wrap. Claim 41 is directed to third patch. Claim 43 requires enclosure for the patches, and claims 44-45 require container or board as a holder. Claim 46 recites more than one first patch. Claim 47 requires releasably attachment of the patches to the holder. Claim 48 recites an intended use of the flexible wrap as to secure first or second patch to the body.

US '358 disclosed therapeutic device featuring a plurality of compartments enclosing a therapeutic substance which may be a refrigerant, which reads on endothermic patch, a heat releasing substance (which reads on exothermic patch), or a high density material or weighed packets (which reads on third patch), the device may be wrapped on various body portions using strap means (abstract; col.4, lines 20-25; col.5, lines 25-26). The device comprises packets that slide easily into compartments of the device, which reads on holder as a container (col.3, lines 1-4). Packets reads on patches claimed by applicants because applicant disclosed patch as "packs, packages,

inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure. The figures show holder that can read on board. The device comprises a plurality of compartments, but any number of compartments may actually be filled with cooling or heating packets or weights for any particular application. The reference disclosed that according to one embodiment wherein cooling or heating packets are removable, i.e. releasably attached (col.3, lines 6-20). A single therapeutic device may be used to cool or heat, simultaneously, two different, but spaced nearby body areas (col.3, lines 26-35). The device is wrapped around the bodily injury by strap means that encircle the therapeutic device (col.5, lines 50-53). The device is flexible, and this implies that the strap is flexible so it can be wrapped around and encircles areas of the body (col.5, lines 1, 10). The limitations of claims 40, 41, 43-48 are met by US '358.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '358 in view of US 6,245,347 ('347).

The teachings of US '358 are discussed under 102 rejection above.

Although US '358 disclosed third type of patch, however, it does not specifically teach an analgesic patch as claimed by claim 42.

US '347 teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and third packet to be provided to injured portion of the body as disclosed by US '358, and replace the third packet with or further add analgesic patch that advantageously accompanied with cooling or heating means as disclosed by US '347, motivated by the teaching of US '347 that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic, with reasonable expectation of having system for providing therapy to part of the body comprising holder, exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug to relieve the pain and be involved in the treatment of the injured part of the body, with successful relief of pain or discomfort of the patient.

Art Unit: 1615

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1615

IG

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PRIMARY EXAMINER